

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

IN RE PHARMACEUTICAL INDUSTRY
AVERAGE WHOLESAL PRICE
LITIGATION

MDL No. 1456

CIVIL ACTION: 01-CV-12257-PBS

Judge Patti B. Saris

THIS DOCUMENT RELATES TO
ALL CLASS ACTIONS

**PLAINTIFFS' MEMORANDUM IN SUPPORT OF MOTION TO AMEND
THE MASTER CONSOLIDATED CLASS ACTION COMPLAINT**

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I. INTRODUCTION

On May 13, 2003, the Court issued its Memorandum and Order (the “Order”) in response to defendants’ motions to dismiss, to strike and for a more definite statement. The Court gave plaintiffs an opportunity to file a motion to amend the Master Consolidated Class Action Complaint (the “MCC”) to cure defects identified in the Order. *See* Order at 47. Accordingly, plaintiffs file the instant motion and memorandum seeking leave to file the Amended Master Consolidated Class Action Complaint (the “AMCC”) that is attached as Exhibit A. For the reasons set forth below, the Court should permit all of the amendments.

II. LEGAL STANDARDS

Fed. R. Civ. P. 15(a) provides that leave to amend “shall be freely given when justice so requires,” a command echoed by the First Circuit. *See Grant v. News Group*, 55 F.3d 1, 5 (1st Cir. 1995). Generally, a motion to amend should be granted absent undue delay, dilatory motive, bad faith, repeated failure to cure deficiencies by amendments previously allowed, undue prejudice to the opposing party or futility of the amendment. *United States ex rel. Franklin v. Pfizer*, 2002 U.S. Dist. Lexis 5761, at *5 (D. Mass. Feb. 6, 2002) (Saris, J.) (denying amendment made five years after case filed) (citing *Foman v. Davis*, 371 U.S. 178, 182, 9 L. Ed. 2d 222, 83 S. Ct. 227 (1962)). “If leave to amend is sought before discovery is complete and neither party has moved for summary judgment, [futility] is gauged by reference to the liberal criteria of Federal Rule of Civil Procedure 12(b)(6),” and the amendment should be permitted “as long as the proposed amended complaint sets forth a general scenario which, if proven, would entitle the plaintiff to relief against the defendant on some cognizable theory.” *Hatch v. Dep’t for Children*, 274 F.3d 12, 19 (1st Cir. 2002).

III. THE COURT SHOULD PERMIT PLAINTIFFS' AMENDMENTS

Plaintiffs review the salient changes that comprise the AMCC below.¹ Because plaintiffs' proposed amendments are timely, made in good faith and are well grounded in fact and law, they should be granted pursuant to Fed. R. Civ. P. 15(a).

A. The AMCC Corrects the Standing Issues Regarding the Association Plaintiffs

The Court ruled that the association plaintiffs did not have Article III standing because the MCC did not allege that the association plaintiffs "purchased a specific drug from a specific company." Order at 44. With respect to association plaintiffs, the AMCC includes five associations as plaintiffs, but identifies which of their members purchased a drug placed at issue in the complaint. AMCC ¶¶ 32-36.

B. The AMCC Adds Two New Union Pension Fund Plaintiffs

Given the dismissal of many association plaintiffs, and in order to satisfy the Court's command that the only proper defendants are companies from which a plaintiff purchased a drug (and to target as many drugs as possible for which defendants' stated an inflated AWP), plaintiffs seek to add two additional union pension fund plaintiffs. They are: (i) the Philadelphia Federation of Teachers, Health and Welfare Fund, and (ii) the Man-U Service Contract Trust Fund. AMCC ¶¶ 30-31. During the Class Period, each of these new plaintiffs – which are both trust funds established and maintained pursuant to Section 302(c)(5) of the Labor Management Relations Act, 29 U.S.C. § 186(c)(5), and employee benefit plans established and maintained pursuant to the Employee Retirement Income Security Act, 29 U.S.C. § 1001 *et seq.* – has been billed for and paid charges for Medicare Part B drugs and has made payments for drugs outside of the Medicare Part B context based on published AWPs. AMCC ¶¶ 30-31. These drugs are identified in Appendix B to the AMCC. These two new plaintiffs have standing under the Court's Order and should be added to the suit.

¹ Plaintiffs emphasize that the summary below does not inventory each and every change made to the MCC. Rather, the purpose of the overview is to direct the Court's attention to the major changes, particularly those made in response to the Court's Order.

C. The AMCC Adds Three New Defendants

The AMCC adds three new defendants, Novartis Pharmaceuticals Corporation (“Novartis”), TAP Pharmaceuticals Products, Inc. (“TAP”), and Together Rx LLC (“Together Rx”). Novartis, TAP and Together Rx are key participants in the Together Card conspiracy discussed *infra*, and Novartis and TAP have reported inflated AWP for drugs included in the Together Card Program. See AMCC ¶¶ 107-08, 125-28, 131 and Appendix A. Accordingly, these defendants should be added to this lawsuit.

D. The AMCC Specifies The Drugs Purchased By Each Plaintiff

The Court ruled that “the allegations in the complaint are insufficient to support a claim of standing under the doctrine of juridical linkage with respect to defendants from which no plaintiff has purchased a drug.” Order at 43. Accordingly, the Court dismissed the following defendants with respect to the Class One claims: Abbott, Baxter, Boehringer, BMS, Braun, SmithKline, Immunex, Johnson & Johnson, Pharmacia, Schering-Plough and Warrick. Order at 47. The Court also dismissed the following defendants with respect to both the Class One and Class Two claims: Amgen, Bayer, Hoffman LaRoche, Merck, Pfizer, Sicor and Johnson & Johnson. *Id.*

In response to this ruling, plaintiffs have identified each drug purchased by each plaintiff from each of these defendants that is placed at issue in this complaint. This information is found in Appendix B to the AMCC. Consequently, all defendants previously dismissed should be reinstated by allowing these amendments.²

E. The AMCC Identifies Each Drug For Each Manufacturer**1. Plaintiffs Have Identified Fraudulent AWP for Approximately 325 Drugs Based on the Limited Information Available**

The Court granted the motion to dismiss “with respect to any drugs that the complaint fails to identify both with respect to name of the drug and the allegedly fraudulent published

² Merck has not been named in the AMCC.

AWP for the drug.” Order at 46-47. In response, plaintiffs have painstakingly compiled for each defendant the following information for each drug for which relief is presently sought in the AMCC: (i) brand name of the drug (if applicable); (ii) the drug’s generic name; and (iii) the drug’s therapeutic category/usage. A table containing this information for each defendant is found in Part V of the AMCC. For examples, *see* ¶¶ 201 (Abbott); 217 (Amgen); 231 (AstraZeneca); 250 (Aventis). In addition, Appendix A contains a table itemizing fraudulent AWP’s for each of these drugs. The table is organized by defendant and drug name and provides the fraudulent AWP for each drug as reported by each defendant in the month of December for a six-year period from 1997 through 2002. This information satisfies the Court’s command that the AMCC “identify [the] name of the drug and the allegedly fraudulent published AWP for the drug.”

F. The AMCC Includes Additional Defendant-Specific Allegations

In addition to the foregoing, the AMCC in Part V also contains many new examples of specific misconduct for most defendants. These new allegations have been added to conform to the evidence contained in defendants’ document production, as well as new public information recently obtained.

G. The AMCC Contains Additional Allegations Regarding Multi-Source/Generic Drugs

The Court dismissed “all multi-source generic drugs from the complaint, because plaintiffs have not framed their claims to include such drugs” and invited plaintiffs to amend to add “a theory that captures multi-source generic drugs.” Order at 46. The AMCC now contains substantially augmented allegations regarding multi-source and generic drugs, as the Court requested. *See* AMCC ¶¶ 179-90. Indeed, as the new allegations demonstrate, AWP fraud is most exacerbated for generic drugs or for brand name drugs for which there are biological or therapeutic equivalents, sometimes resulting in an AWP over 50,000% over actual costs. AMCC ¶ 187.

In the private payor arena, generic drug reimbursement is closely tied to the published AWP for a generic drug. Generic drug makers are able to push market share for their generic drugs by intentionally increasing the published AWP for a generic drug with the intention to create a profit margin for others in the distribution chain. That profit margin is taken advantage of either directly (through reimbursement based upon AWP for some plans and in some channels) or indirectly on the AWP based upon the establishment of a maximum allowable cost or “MAC” that is tied to the AWP. AMCC ¶ 183.

In the public payor arena under Medicare Part B, multi-source drugs or biologicals are also reimbursed on the basis of AWP, which is equal to the lesser of the median AWP of all of the generic forms of the drug or biological, or the lowest brand name product AWP. Because reimbursement is pegged to the AWP, drug makers act in unison by elevating the AWP for all generic drugs, thereby inflating the amount of the reimbursement that occurs through Medicare Part B, including the Medicare co-payment through Part B. AMCC ¶ 184.

In addition to general allegations of AWP fraud in the multi-source and generic context, the AMCC also sets forth many specific examples for specific defendants. *See, e.g.*, AMCC ¶¶ 187 (summary table); 208 (Abbott); 431 (Immunex); 534 (Watson). Documents produced by defendant generic manufacturers show that they are aware of the AWP reported by their competitors and of the actual sales price of their generic competitors and that they manipulate their own AWP in order to gain or maintain a competitive advantage in the market for their generic products. Each defendant generic maker or distributor competes by inflating its AWP and thereby inflating the median AWP. The natural and expected result of this “leap frogging” of increasing AWP is that multi-source drugs have some of the highest spreads of any drugs. AMCC ¶ 187.

In sum, the evidence garnered to date overwhelmingly supports the inclusion of multi-source and generic drugs in this lawsuit.

H. The RICO Amendments: Counts I and II Of The AMCC Properly Assert Civil RICO Claims Against Defendants

In its Order, the Court granted defendants’ motion to dismiss plaintiffs’ civil RICO claims, holding that each of Counts I-IV of the MCC failed to “allege a viable RICO enterprise.” Order at 12. As set forth below, the allegations of plaintiffs’ AMCC satisfy this Court’s concerns with the RICO “enterprise” allegations. Counts I and II of the AMCC properly assert claims against various defendants for violations of Section 1962(c) of RICO, 18 U.S.C. § 1962(c), and those claims properly allege the existence of association-in-fact enterprises in accordance with First Circuit precedent and this Court’s Order.³

1. Overview of the AMCC Civil RICO Claims

Section 1962(c) of RICO makes it “unlawful for any person employed by or associated with any enterprise engaged in, or the activities of which affect, interstate or foreign commerce, to conduct or participate, directly or indirectly, in the conduct of such enterprise’s affairs through a pattern of racketeering activity. . . .” 18 U.S.C. § 1962(c). Thus, plaintiffs or the government must prove the same elements: (i) an enterprise existed; (ii) the enterprise participated in, or its activities affected, interstate commerce; (iii) the defendant was employed by or was associated with the enterprise; (iv) the defendant conducted or participated in the conduct of the enterprise; (v) through a pattern of racketeering activity. *United States v. Marino*, 277 F.3d 11, 33 (1st Cir.) (citing *United States v. Shifman*, 124 F.3d 31, 35 (1st Cir. 1997)), *cert. denied*, 536 U.S. 948 (2002); *see also North Bridge Assocs., Inc. v. Boldt*, 274 F.3d 38, 42 (1st Cir. 2001). The AMCC alleges each of these elements, as summarized in the following chart:

Elements of Civil RICO Claims:	<u>Count I</u> (¶¶ 619-46)	<u>Count II</u> (¶¶ 647-79)
“Persons”	¶ 621	¶¶ 649
“Enterprise(s)”	¶¶ 621-28 (Publisher Enterprises)	¶¶ 651-61 (PBM Enterprises)

³ And as discussed in the next section of this memorandum, Count VIII also properly asserts claims against certain of the defendants for creating and conducting the affairs of Together Rx, LLC (“Together Rx”), in violation of Section 1962(c) and (d) of RICO, 18 U.S.C. § 1962(c)-(d).

Elements of Civil RICO Claims:	Count I (¶¶ 619-46)	Count II (¶¶ 647-79)
“Racketeering Activity”	¶¶ 629-33 (Mail/Wire Fraud)	¶¶ 662-66 (Mail/Wire Fraud)
“Pattern of Racketeering Activity”	¶¶ 637-41	¶¶ 670-74
“Conduct” of Enterprise(s)	¶¶ 623-27, 634-36	¶¶ 652-60, 667-69
“Defendants’ Motive”	¶¶ 642-43	¶¶ 675-76
“Plaintiffs’ Injury”	¶¶ 644-46	¶¶ 677-79

Because the Court’s order addressed only the enterprise requirement, the discussion below focuses primarily on enterprise issues.

2. The Enterprises

The AMCC does *not* allege the existence of two types of enterprises struck by the Court, the “AWP Enterprises”⁴ and the Third-Party Payor/Victim Enterprises.^{5,6} Instead, Counts I and II of the AMCC allege only the existence of a series of Manufacturer-Publisher and Manufacturer-PBM enterprises, respectively. These enterprises, which were originally alleged in the MCC, have been retooled to cure the deficiencies found by the Court. The salient features of the enterprises pled in the AMCC and the relevant parties are summarized as follows:

⁴ Count I of the MCC alleged the existence of 21 “AWP Enterprises,” which the Court described as “consisting of a single defendant pharmaceutical company and all the medical providers that prescribe its drugs with a reported AWP.” Order at 15. The Court held that these “hub-and-spoke” configurations failed to allege a RICO enterprise. *Id.* at 16-20.

⁵ Counts I, II, III and IV of the MCC alleged the existence of Third-Party Payor/Victim Enterprises. As to each claim, plaintiffs alleged that their employee health plans are “enterprises” which were “victimized when they made fraudulently inflated payments for drugs, based on defendants’ falsely inflated AWP’s.” Order at 22. The Court believed that plaintiffs had not adequately alleged that defendants operated or managed the Third-Party Payor/Victim Enterprises within the meaning of § 1962(c). *Id.* at 24.

⁶ Although these enterprises have not been included in the AMCC, plaintiffs respectfully disagree with the Court’s ruling on these points and are preserving their rights to appeal their dismissal.

Count	Description of Liable “Persons” and Relevant Parties	RICO Enterprise(s) Identified	RICO Violations
Count I	22 Defendant Drug Manufacturers are named as liable “persons.” Three Publishers of AWP’s – Thomson; First DataBank; and Facts & Comparisons – are identified.	As to each of the 22 Defendant Drug Manufacturers, there are three separate association-in-fact enterprises, consisting of one manufacturer and one publisher (Example: “Abbott-Thomson Enterprise.”)	§ 1962(c)
Count II	22 Defendant Drug Manufacturers are named as liable “persons.” Four Pharmacy Benefit Managers – Advance PCS; Caremark Rx; Express Scripts; and Medco Health – are identified.	As to each of the 22 Defendant Drug Manufacturers, there are four association-in-fact enterprises, consisting of one manufacturer and one PBM. (Example: “Abbott-AdvancePCS Enterprise.”)	§ 1962(c)

“Enterprise” is defined broadly to include “any individual partnership, corporation, association, or other legal entity, and any union or group of individuals associated in fact though not a legal entity.” 18 U.S.C. § 1961(4). Thus, to satisfy the “enterprise” element, plaintiffs must allege “either the existence of a legal entity, such as a corporation, or that a group of individuals were associated-in-fact.” *Aetna Cas. & Sur. Co. v. P&B Autobody*, 43 F.3d 1546, 1557 (1st Cir. 1994). An association-in-fact enterprise is an “ongoing organization,” whether “formal or informal,” with members “functioning as a continuing unit,” which is “separate and apart from the pattern of racketeering in which it engages.” *United States v. Turkette*, 452 U.S. 576, 583 (1981). An association-in-fact RICO enterprise may consist of “two or more legal entities,” or “two legal entities and two individuals.” *United States v. London*, 66 F.3d 1227, 1243 (1st Cir. 1995). The First Circuit has expressly rejected an “ascertainable structure” enterprise requirement. *See United States v. Patrick*, 248 F.3d 11, 18-19 (1st Cir. 2001) (“Since

Congress intended the term ‘enterprise’ to include both legal and criminal enterprises, . . . and because the latter may not observe the niceties of legitimate organizational structures, we refuse to import an ‘ascertainable structure’ requirement into jury instructions.”), *cert. denied*, 534 U.S. 1043, and *cert. denied*, 535 U.S. 910 (2002); *London*, 66 F.3d at 1244 (association-in-fact enterprise consisting of corporation and sole proprietorship engaged in bookmaking and extortion).

As set forth below, as to each of the new association-in-fact enterprises that are alleged in Counts I and II of the AMCC, plaintiffs have specifically alleged the relevant criteria to demonstrate the existence of the enterprise and identify its associates, as required by this Court and by the First Circuit. *See* Order at 15.

a. The “Publisher Enterprises”

Counts II and III of the MCC alleged the existence of 22 “Publisher Enterprises,” which this Court described as “associations-in-fact comprised of each of the [drug manufacturers] and the publishers that reported their AWP.” Order at 21. As previously alleged, each of these “Publisher Enterprises” consisted of one pharmaceutical company as the “hub” and “each of the [four] major publishers that reported the AWP provided to them by the [pharmaceutical] company as the spokes.” *Id.* The Court found that this definition suffered from a failure of connectedness and common purpose, *id.* at 21-22, the so-called “hub-and-spoke” problem.

To eliminate the “hub-and-spoke” problem, Count I of the AMCC now alleges, for each of the defendants, a separate association-in-fact enterprise consisting of a single pharmaceutical company and a single publisher (a “Manufacturer-Publisher Enterprise”). For example, in Count I, Abbott is alleged to have been a member of three separate association-in-fact Manufacturer-Publisher Enterprises: The Abbott-Thomson Medical Enterprise; the Abbott-First DataBank Enterprise; and the Abbott-Facts & Comparisons Enterprise. As a result, Count I of the AMCC now alleges 66 separate Manufacturer-Publisher Enterprises. Thus, the rimless wheel has been eliminated.

As to each of the Manufacturer-Publisher Enterprises and the specific Defendant Drug Manufacturer and Publisher that are the entities associated-in-fact, plaintiffs allege (i) their “common purpose[s]”; (ii) their financial ties and how they coordinate their activities (reporting and publishing AWP); and (iii) how they share information on a regular basis. AMCC ¶¶ 624-27, 634-36. The allegations as to common purpose, financial ties and coordination have been amplified in the AMCC, which now alleges that each of the Publishers was aware of the Defendant Drug Manufacturers’ AWP Scheme, was a knowing and willing participant in that scheme, and reaped profits from that scheme. *Id.* Furthermore, each Publisher was well aware that it was publishing inflated AWP. For instance, at some point prior to 1992 the Publishers in many instances obtained AWP themselves by surveys that they conducted. Based on this survey experience, the Publishers know that the AWP being reported by the manufacturers are not accurate. AMCC ¶ 626.

The Publishers’ knowledge of various government agency reports of AWP inflation also highlights their participation in the wrongdoing and the common purpose that the Publishers share with the manufacturers. With one exception, the Publishers did not change or challenge the self-reported AWP, but continued blindly accepting the requested AWP, notwithstanding their knowledge of the government reports. AMCC ¶ 626. The one exception just mentioned involves the reporting by Dey of inflated AWP. When the State of Texas prosecuted Dey for its AWP practices, and when other states began focusing on Dey, the Publishers stopped accepting Dey’s reported AWP and published a different, far lower AWP. They withdrew from the Dey enterprise due to fear that they would be sued if they continued to publish Dey’s false AWP. This, in turn, prompted a lawsuit by Dey alleging that the Publishers were treating Dey *differently* than they were treating all other manufacturers. In other words, Dey was complaining of the others being allowed to continue the scheme while it could not. AMCC ¶ 626.

The Publishers also have an economic incentive to merely report the AWP's provided to them by the manufacturers, because to do otherwise would require the Publishers to spend money to extensively survey actual sales prices in the market. By simply republishing what is submitted to them by the drug manufacturers, the Publishers save on expenses and consequently reap greater profits. AMCC ¶ 626. Thus, each of the Manufacturer-Publisher Enterprises has a common purpose of perpetuating the use of AWP's as a benchmark for reimbursement in the pharmaceutical industry. AMCC ¶ 624.

These allegations satisfy the criteria for association-in-fact enterprises previously identified by the Court, *see* Order at 13-15, and by the First Circuit in the above-referenced reported cases. Accordingly, the amendment should be allowed.

b. The "Pharmacy Benefit Managers Enterprises"

Count IV of the MCC alleged the existence of "PBM Enterprises," comprised of "each individual drug manufacturer and all the Pharmacy Benefit Managers that exploit the 'spread' between the reported AWP's and the actual price of covered drugs." Order at 21. Sixteen PBM Enterprises were alleged: "[e]ach . . . is said to be comprised of an individual drug company at the hub (i.e. Abbot [sic], Amgen, etc.) and a number of *unnamed* pharmacy benefit managers as spokes." *Id.* (emphasis added). Thus, the Court found the same "hub-and-spoke" problem because the MCC "fail[ed] to allege facts which would support an entity consisting of all the PBMs joined with a drug company in a common purpose." *Id.*

To address these concerns, Count II of the AMCC identifies the four largest PBMs by name: AdvancePCS; Caremark Rx; Express Scripts; and Medco Health.⁷ To eliminate the "hub-and-spoke" problem, Count II alleges, for each of 22 Defendant Drug Manufacturers, a separate association-in-fact enterprise consisting of a single pharmaceutical company and a single PBM. For example, in Count II, Abbott is alleged to have been a member of four separate Manufacturer-PBM Enterprises: The Abbott-AdvancePCS Enterprise; the Abbott-Caremark Rx

⁷ These four PBMs comprise 85% of the market served by PBMs.

Enterprise; the Abbott-Express Scripts Enterprise; and the Abbott-Medco Health Enterprise. Count II now alleges 88 separate Manufacturer-PBM Enterprises.

As to each of the PBM Enterprises and the specific Defendant Drug Manufacturer and PBM that are the entities associated-in-fact, plaintiffs allege (i) their “common purpose[s]”; (ii) their financial ties and how they coordinate their activities (reporting and publishing AWP); and (iii) how they share information on a regular basis. AMCC ¶¶ 651-55, 667-69. Indeed, each PBM Enterprise had a common purpose of perpetuating the use of AWP as a benchmark for reimbursement in the pharmaceutical industry. The manufacturing defendants had this as a purpose because, without the use of inflated AWP as an industry price setting benchmark, they would not be able to push the spread to those in the distribution chain. AMCC ¶ 654. The PBMs share this common purpose, because they are subject to a great deal of control from the manufacturers. PBMs turn to drug manufacturers for hidden profit-making schemes that fall into three general categories: (i) garnering rebates and other “soft dollars” from drug manufacturers that the PBMs, to a large extent, conceal; (ii) pocketing secret spreads between actual drug costs and the prices charged to health plans and their members; and (iii) keeping secret discounts provided by the drug manufacturers in association with the PBMs’ mail order operations. In the aggregate, these money-making schemes constitute the bulk of the PBMs revenues, far surpassing the PBMs’ traditional primary revenue resource of charging fees for administering claims. AMCC ¶ 654. As a result of their reliance on the manufacturers for the bulk of their revenue streams, PBMs took instructions and commands from the manufacturers regarding the use of AWP, not only so that they could keep part of the spread, but also so as to continue to earn rebates and other soft dollars from the manufacturers. AMCC ¶ 657.

These allegations satisfy the criteria for association-in-fact enterprises previously identified by the Court, *see* Order at 13-15, and by the First Circuit in the above-referenced reported cases. Accordingly, the amendment should be allowed.

I. The AMCC Adds Allegations And Claims That Certain Defendants Affirmatively Conspired To Raise AWP

1. The Together Card Conspiracy

The AMCC includes new allegations of a conspiracy among certain defendants to raise and fix AWPs in connection with drugs covered by the “Together Rx Card Program” (“Together Card”). See ¶¶ 592-94, 604-18, 692-725, 734-41. Although new, these allegations – which have been extensively investigated over the course of several months – are closely related to the core AWP fraud at issue in this suit because the inflation of AWPs is the touchstone of the Together Card conspiracy.

In 2002, certain defendants – Abbott, AstraZeneca, Aventis, BMS, GSK, Novartis and Johnson & Johnson, through its subsidiary defendants Janssen and Ortho-McNeil, and later joined by TAP (the “Together Card Defendants”) – announced a new pharmaceutical alliance, Together Rx, that was formed to provide Medicare enrollees who have no prescription drug coverage with a “Together Rx Card” that would, ostensibly, provide these needy seniors with discounts on over 150 widely prescribed brand name drugs, many of which are utilized to treat conditions that disproportionately affect older Americans. AMCC ¶¶ 543, 562.⁸ These Together Card Defendants touted the program as a means to save qualifying seniors as much as 20-40% of the drug prices that they currently paid. AMCC ¶ 579.

Unfortunately, these defendants used the Together Card backdrop to fix, raise, and artificially maintain reimbursement levels for their prescription drug products, including reimbursement levels outside of the Together Card Program. As a result of their desire to avoid the financial burden attendant to that program, the Together Card Defendants conspired and agreed to simply impose the burden of Together Card product in administrative costs right back upon end payors consumers by raising reimbursement or end-payor prices (the AWPs) in relation

⁸ The specific drugs that are part of the Together Card allegations are set forth in Appendix A to the AMCC. These 150 drugs account for approximately 900 drug/dose combinations.

to the actual costs to wholesalers, pharmacies and mail order companies (known as the “WAC”). AMCC ¶¶ 584-94. Thus, before their joint launch of the Together Card, defendants agreed to fix, raise and maintain the AWP/WAC “spread” on nearly every one of the over 150 drugs included in the Together Card Program. Prior to the formation of the Together Card alliance, the AWP for the Together Card Drugs reflected an AWP pricing spread of roughly 20% based on the WAC divided by AWP. Following the alliance, the AWP pricing spreads for these same drugs increased to 21%-26%. In short, the Together Card Defendants provided Medicare beneficiaries with a purported “discount” off the AWP of their Together Card Drugs – but only after they had agreed to fix, raise and maintain certain AWP spreads. AMCC ¶ 590.

2. The Together Card Classes

The AMCC contains separate class action allegations for the Together Card scheme, *see* ¶¶ 604-18, and alleges the existence of two classes as follows:

- *The Nationwide End-Payor Together Card Class:* All person or entities in the United States and its territories who paid any portion of the purchase price for, or who reimbursed any portion of the purchase price of, a drug covered by the Together Rx Program on the basis, in whole or in part, on the published average wholesale price during the time period January 1, 2002 up to and including the present.
- *The Indirect Purchaser States End-Payor Together Card Class:* All persons or entities in the indirect purchaser states who paid any portion of the purchase price for, or who reimbursed any portion of the purchase price of, a drug covered by the Together Rx Program on the basis, in whole or in part, on the published average wholesale price during the time period January 1, 2002 up to and including the present.

AMCC ¶ 605

The remainder of the Together Card class allegations pleads each requisite element of Fed. R. Civ. P. 23. *See* AMCC ¶¶ 606-18.

3. The Together Card Conspiracy Violates State and Federal Antitrust Law

These actions are classic violations of the Sherman and Clayton Acts, 15 U.S.C. §§ 1 and 16, respectively. As a result of the conspiracy, and because raising the AWP affects all patients who consume the drugs covered by the Together Card Program – and not just Together Card

Drug enrollees – all plaintiffs and the Nationwide End-Payor Together Card Class paid higher prices for the drugs included in the Together Card program than they would have paid but for these defendants’ anticompetitive conduct, and they have been injured in their business or property. Accordingly, the AMCC contains two antitrust counts, Count V for injunctive relief under Section 16 of the Clayton Act, and Count VI for treble damages under Section 1 of the Sherman Act.

To state a valid Section 16 claim under the Clayton Act, plaintiffs must allege (and ultimately prove) threatened loss or damage “of the type the antitrust laws were designed to prevent and that flows from that which makes defendants’ acts unlawful.” *Cargill, Inc. v. Monfort of Colorado, Inc.*, 479 U.S. 104, 113 (1986) (quoting *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc.*, 429 U.S. 477, 489 (1977)); see also *Cia. Petrolera Caribe, Inc. v. Arco Caribbean, Inc.*, 754 F.2d 404, 408 (1st Cir. 1985) (reciting elements of a Section 16 Clayton Act claim). As alleged in the AMCC, plaintiffs and members of the Nationwide Together Card End-Payor Class suffered antitrust injury in that they paid higher prices for the Together Card Drugs than they would have paid but for defendants’ anticompetitive conduct. AMCC ¶¶ 697, 703, 707. The overpayments were a direct result of the Together Card Defendants’ conspiracy to raise, fix and maintain the AWP spreads of the Together Card Drugs, in violation of Section One of the Sherman Act. AMCC ¶ 703; see also *Brunswick*, 429 U.S. at 488 (requiring allegations as to the injury and effect of the antitrust conspiracy on competition).

In order to maintain a Section One claim, plaintiffs must demonstrate a contract, combination or conspiracy among two or more separate entities that unreasonably restrains trade. See 15 U.S.C. § 1; see also *Monsanto Co. v. Spray-Rite Serv. Corp.*, 465 U.S. 752, 764 (1984) (noting that concerted action to set prices is per se illegal under the Sherman Act); *Standard Oil Co. v. United States*, 221 U.S. 1, 52 (1911) (reciting the elements of a Section 1 Sherman Act claim); *George R. Whitten, Jr., Inc. v. Paddock Pool Builders, Inc.*, 508 F.2d 547, 557 (1st Cir. 1974) (summarizing a conspiracy as “a plurality of actors concerting their efforts toward a

common end”). A Section One conspiracy involves a “conscious commitment to a common scheme designed to achieve an unlawful objective.” *See Monsanto*, 465 U.S. at 764. Proof of a conspiracy requires evidence that tends to exclude the possibility that the conspirators were acting independently. *See id.*

As alleged in the AMCC, sometime in 2001 or 2002, the exact date of which is not yet known, the Together Card Defendants entered into a conspiracy to raise, fix and maintain the AWP spreads for Together Card Drugs. AMCC ¶¶ 584-600. The conspiracy presented itself to the public under the guise of Together Rx LLC, an alliance formed by the founding Together Card Defendants, purportedly to provide drug discounts to seniors, but in effect, was a vehicle to facilitate this conspiracy by enabling defendants to share pricing information. *Id.*

The impact of the scheme on AWP spreads was more than coincidental and clearly out of line with the normal course of business in the pharmaceutical industry. The AMCC delineates the extensive scope and the effectively simultaneous timing of the AWP spread changes following the creation of the alliance. In a historically extraordinary move for the industry, all of the Together Card Defendants changed the AWP spreads on virtually all of their Together Card Drugs, across many therapeutic classes and product lines. AMCC ¶¶ 584-600. Furthermore, the Together Card Defendants’ conduct is inconsistent with their alleged motive. While purporting to reduce the price of prescription drugs, *see, e.g.*, AMCC ¶ 567, the Together Card Program in fact had the opposite result of increasing prices to plaintiffs and the Class. AMCC ¶¶ 697, 703, 707.

Plaintiffs allege that members of the Nationwide Together Card End-Payor Class are direct purchasers in that they are the first and only ones in the distribution chain that actually pay and are harmed as a result of the agreement to fix reimbursement rates and the AWP spread. AMCC ¶ 730. In the event that plaintiffs and the Class are deemed indirect purchasers, they alternatively allege Count VII for relief under the antitrust laws of the Indirect Purchaser States on behalf of the Indirect Purchaser States End-Payor Class.

4. The Together Card Conspiracy Violates RICO

The Together Card Defendants' conspiracy is also a patent violation of RICO, more specifically 18 U.S.C. § 1962(c)-(d). Consequently, the AMCC contains a RICO count – Count VIII – specifically tailored to the Together Card allegations and containing all of the requisite elements of a RICO violation. The Together Card Defendants are alleged to be “persons” as that term is defined in 18 U.S.C. § 1961(3). AMCC ¶ 711. The count alleges the existence of an entity enterprise – Together Rx – formed by the Together Card Defendants. AMCC ¶ 712. The Together Card Defendants conducted the affairs of the enterprise through, among other things, designing and drafting the promotional and marketing materials for the Together Card Program and disseminating those promotional and marketing materials to consumers nationwide. AMCC ¶ 718. The Together Card Defendants conducted the enterprise's affairs through a pattern of racketeering activity that included thousands of instances of mail and wire fraud within the meaning of 18 U.S.C. §§ 1961(1)(B) and (5). AMCC ¶¶ 713-17, 719-21. These defendants were motivated to fraudulently obtain sales and profits, and their RICO violations directly and proximately injured plaintiffs and members of the Together Card Nationwide End Payor Class in their business and property through the payment of inflated reimbursements for the drugs. AMCC ¶¶ 722-25. This claim also alleges that these defendants conspired to conduct the affairs of Together Rx, in violation of Section 1962(d) of RICO. AMCC ¶ 710.

J. The Complaint Adds Two Conspiracy Counts

Liability for civil conspiracy arises when two or more parties perform a tortious act in concert and pursuant to a common design, or when one party knows that the other's conduct constitutes a breach of duty and gives substantial assistance or encouragement. *See, e.g., Kyte v. Philip Morris, Inc.*, 408 Mass. 162, 167 (1990). The AMCC pleads two civil conspiracy claims that satisfy these pleading requirements as shown below.

1. The Defendant Drug Manufacturers Conspired with the PBMs

Count IX of the AMCC contains a new claim challenging the conspiracy formed between each Defendant Drug Manufacturer and each PBM that had the common purpose of perpetuating a reimbursement system based on AWP, because such a system financially benefits *both* the manufacturer and the PBM. AMCC ¶ 729. The Defendant Drug Manufacturers deliberately and fraudulently overstate the AWP for their AWPIDs, thereby creating a “spread” based on the inflated figure in order to induce each of the PBMs to advocate and favor that particular Defendant Drug Manufacturer’s drugs to the members of that PBM’s clients. Each of the PBMs then billed their clients for the particular Defendant Drug Manufacturers’ AWPIDs based on the inflated AWP, which did not reflect the true price paid by the PBMs for the AWPIDs. All of these acts – and more – were done as part of a conspiracy to deceive payors, in violation of applicable state consumer protection laws and the common law of fraud. All of these acts were also done in violation of Medicare anti-fraud kickback statutes and were done pursuant to acts of unlawful instances of mail and wire fraud. AMCC ¶ 729. The AMCC identifies each conspiracy, which consists of a Defendant Drug Manufacturer and each PBM. AMCC ¶ 728.

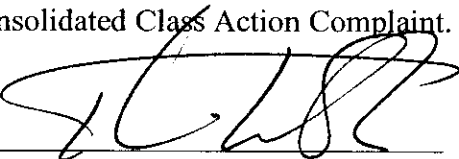
2. The Together Card Defendants Have Engaged in a Common Law Civil Conspiracy to Inflate AWP

Finally, the Together Card Defendants’ conduct also constitutes a common law civil conspiracy. Each of the Together Card Defendants joined in a conspiracy to fix, set and/or maintain the spread between their reported AWP and WAC, and each agreed to raise their AWP prior to implementation of the Together Card Program. AMCC ¶ 736. Each Together Card Defendant also agreed to publish AWP that were inflated. Each of these defendants also knew that the other defendants’ AWP were often inflated, so each was aware that by agreeing to raise and fix AWP, they were perpetuating the use of inflated AWP on a nationwide basis. AMCC ¶ 736. As a part of their common plan, the Together Card Defendants each committed unlawful act or acts in furtherance of this conspiracy, including acts violating the Sherman Act,

state consumer protection laws, and RICO. Accordingly, the AMCC contains a new count – Count X – for common law civil conspiracy.

IV. CONCLUSION

For the foregoing reasons, the Court should accept for filing Plaintiffs' Amended Master Consolidated Class Action Complaint.

By 

DATED: June 12, 2003.

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